

SPECIFICATION - SUBSTITUTE SHEETS 1-6A

INJECTION DEVICE

FIELD OF THE INVENTION

The invention relates to an injection device comprising a container for reception of a cartridge which contains an injection fluid and on whose proximal end an injection needle can be mounted.

BACKGROUND

An injection device of this kind is known from DE 42 23 958-A1 and corresponding U.S. Patent 5,480,387, BECHTOLD & GABRIEL. The injection device depicted and described therein operates very reliably and precisely, but is less suitable for the use of large cartridges comprising larger quantities of injection fluid.

SUMMARY OF THE INVENTION

It is therefore an object of the invention to make a new injection device available.

This object is achieved in one manner by using a special coupling to transfer at least a portion of axial movement of a plunger to the container. As a result of the frictionally engaging connection in the manner of a slip coupling, during an injection the container first follows the axial movement of the plunger until the container has reached its proximal end position. The frictionally engaging connection between plunger and container then releases, and allows an expulsion of the preset dose of injection fluid by means of the plunger, which then moves independently of the container.

The stated object is achieved in a different manner by using a first coupling which is deactivated in a distal position of a setting member, and a second coupling which is activated in an entire axial region between the distal and proximal end positions of a guide member. An injection device of this kind has a simple configuration and operates very reliably and

comfortably for the patient.

The stated object is achieved in a different manner by using a cocking spring to displace a setting member and by guiding axial movement of the components using barrel-mounted splines. An injection device of this kind combines high precision with simple operation and compact design.

Other ways of achieving the stated object are involve dose setting by modifying an axial spacing Y between a setting member and a container, and by using a drive connection between a guide member and the container which limits transfer of torque between these components. The principle of modifying axial spacing Y is highly suitable for injection devices with an automatic injection sequence, and the principle of limiting transfer of torque is particularly "foolproof" when a used cartridge needs to be replaced with a new one.

The stated object is achieved in another manner by allowing a dose-setting apparatus to move axially, and having the apparatus, in its proximal end position, be out of engagement. Because the setting member is not in engagement with the dose-setting apparatus when the latter is in its proximal end position, the setting member can there conveniently be reset into its zero position, either manually or preferably automatically, for example by means of a return spring.

In this context, it is particularly advantageous for the dose-setting apparatus to be out of engagement in its distal end position. The result is that a dose setting is not possible when the dose-setting apparatus is in the distal end position, but is possible only after leaving that end position. This is important because in this fashion, improper operation due to "playing around" with the setting member can be prevented. This counteracts improper dose setting, and thus constitutes a valuable safety feature.

BRIEF FIGURE DESCRIPTION

Further details and advantageous developments of the invention are evident from the exemplary embodiments described hereinafter and depicted in the drawings, which are in no way to be understood as a limitation of the invention.

In the drawings:

FIG. 1 is a three-dimensional depiction of an injection device according to the present invention, as an overview depiction;

FIG. 2 is a side view of the injection device of FIG. 1 in which cocking cap 56 is unscrewed and depicted next to the device;

FIG. 2A schematically depicts a development of a scale usable in an injection device according to the present invention;

FIG. 3 is a depiction analogous to FIG. 1, a proximal segment of the barrel being depicted in section;

FIG. 4 is a depiction of the injection device after an injection, the proximal part being depicted in longitudinal section;

FIG. 5 is an exploded, three-dimensional depiction of components of the proximal part of the injection device;

FIG. 6 is an exploded, three-dimensional depiction which shows various components of the middle part of a device according to the present invention;

FIG. 7 is an exploded, three-dimensional depiction analogous to FIG. 6, which also shows parts of a device according to the present invention;

FIG. 8 is a three-dimensional, enlarged, depiction of a preferred form of a plunger that can be used in the present invention;

FIG. 9 is an exploded, three-dimensional depiction of components of the distal part of the injection device, in a depiction analogous to FIGS. 6 and 7 but at a larger scale;

FIG. 10 is a longitudinal section through a part which forms, inter alia, a clip that serves as trigger for an injection;

FIG. 11 is a longitudinal section through the setting knob of an injection device according to the present invention;

FIG. 12 is a side view of a component of a setting sleeve that is used for dose setting in an injection device according to the present invention;

FIG. 13 is a greatly enlarged depiction of the parts of a setting sleeve which is used for dose setting in an injection device according to the present invention;

FIG. 14 is a three-dimensional depiction of a front and a rear adapter part, in a depiction enlarged as compared to FIG. 6;

FIG. 15 is a longitudinal section through various parts that are arranged in the barrel of the injection device, to explain their functional interaction;

FIG. 16 is a depiction of an injection device according to the present invention in which cocking cap 56 is screwed on but the patient has forgotten to insert an injection needle; the device cannot be cocked;

FIG. 17 is an enlarged depiction of detail XVII of FIG. 16;

FIG. 18 is a depiction analogous to FIG. 15, emphasizing various couplings K1 through K10 which, in their functional interaction, contribute to the mode of operation of the injection device according to the present invention;

FIG. 19 is a longitudinal section through an injection device according to the present invention in its cocked position, i.e. in the position shown in FIGS. 1 and 3;

FIG. 20 is a section viewed along line XX-XX of FIG. 19;

FIG. 21 is a section viewed along line XXI-XXI of FIG. 19;

FIG. 22 shows a longitudinal section through an injection device according to the present invention, in its cocked position and after unscrewing the cocking cap; this position corresponds

to the position of FIG. 2;

FIG. 23 is a longitudinal section analogous to FIG. 22, except that an injection dose has been set;

FIG. 24 is a longitudinal section through an injection device according to the present invention during the first phase of an injection (needle inserted, but before expulsion of injection fluid);

FIG. 25 is a longitudinal section analogous to FIG. 24 but during the second phase of an injection (expulsion of injection fluid after insertion of the needle);

FIG. 26 is a longitudinal section depicting the beginning of a cartridge replacement;

FIG. 27 is a depiction which, continuing from FIG. 26, shows a further phase of cartridge replacement;

FIG. 28 is a depiction showing a phase of cartridge replacement subsequent to FIG. 27;

FIG. 29 is an enlarged depiction of detail XXIX of FIG. 28 which shows the latching of plunger 108 in its distal end position;

FIG. 30 is a schematic depiction showing how a used cartridge 52 is removed from cartridge holder 80;

FIG. 31 shows how a new cartridge is introduced into cartridge holder 80;

FIG. 32 shows how the cartridge holder just loaded (as shown in FIG. 31) is screwed onto the injection device;

FIG. 33 shows the phase subsequent to FIG. 32, i.e. the screwing on of the proximal barrel part and the operations occurring in that context;

FIG. 34 is a depiction of a variant in which, as compared to FIG. 1, a plurality of round holes 54A are used as the viewing window;

FIG. 35 is a plan view, viewed in the direction of arrow XXXV, of FIG. 34 but at a scale enlarged relative to FIG. 34;

FIG. 36 is a schematic depiction of splines 220 of setting sleeve 151 and of the interaction between those splines and a latching member 184 during dose setting prior to an injection;

FIG. 37 is a three-dimensional, exploded depiction of parts that play a role in cartridge replacement; and

FIGS. 38 through 40 provide a synoptic depiction to explain the manner of operation of couplings K4 and K5 in various operating states of an injection device according to the invention.

#### DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS:

In the description below, the terms "proximal" and "distal" are used in the manner usual in medicine:

"Proximal" = the end facing toward the patient, i.e. in FIG. 3 the lower end of the injection device comprising the needle.

"Distal" = the end remote from the patient, i.e. the upper end in FIGS. 1 and 2.

FIG. 1 depicts, in three-dimensional and schematized form, an injection device 30 according to the present invention. The latter has at its distal end a setting knob 32 that, by rotation in the direction of an arrow 34, makes possible a dose setting if the device is in its position as shown in FIG. 2. (In the position as shown in FIG. 1, dose setting is not activated.) Knob 32 is arranged rotatably in a tubular distal barrel part 36 in which an elongated latch opening 38 is present and on which a resilient clip 40 is mounted. Located in clip 40 is a magnifier 42 for reading off the dose that is set. Clip 40 has a radially inwardly projecting protrusion 44 that serves to trigger an injection and is located opposite elongated latch opening 38.

Adjoining distal barrel part 36 in the proximal direction is an annular part 46 that is immovably joined to barrel part 36. This is followed, in the proximal direction, by a middle barrel part 48. Adjoining this in the proximal direction is a proximal barrel part 50 which receives a cartridge 52 comprising a fluid

53 to be injected (FIG. 4) and is equipped with at least one viewing window 54 through which the fill level of cartridge 52 can be observed.

Advantageously, as shown in FIG. 34, a plurality of small orifices 54A is used as the viewing window. This has the advantage that the patient's fingers cannot reach through window 54 and thereby slow down the motion of cartridge 52 during injection, but that the fill level of cartridge 52 can be very easily observed visually.